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COMMENTARIES

# NICE's Selective Application of Differential Discounting: Ambiguous, Inconsistent, and Unjustified

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ABSTRACT

The National Institute for Health and Clinical Excellence (NICE) recently recommended differential discounting of costs and health effects in the economic appraisal of health care interventions in certain circumstances. The recommendation was published in an amendment to NICE's Guide to the Methods of Technology Appraisal. The amendment states that differential discounting should be applied where "treatment effects are both substantial in restoring health and sustained over a very long period (normally at least 30 years)." Renewed interest in differential discounting from NICE is welcome; however, the recommendation's selective application of differential discounting raises a number of concerns. The stated criteria for applying differential discounting are ambiguous. The rationale for the selective application of differential discounting has not been articulated by NICE and is questionable. The selective application of differential discounting leads to several inconsistencies, the most concerning of which is the lower valuation of health gains for those with less than 30 years remaining life expectancy, which can be interpreted as age discrimination. Furthermore, the discount rates chosen by NICE do not appear to be informed by recent advances in the theoretical understanding of differential discounting. NICE's apparent motivation for recommending differential discounting was to ensure a favorable cost-effectiveness ratio for a pediatric oncology drug. While flexibility may be appropriate to allow some interventions that exceed conventional cost-effectiveness thresholds to be adopted, the selective adjustment of appraisal methods is problematic and without justification.

*Keywords:* differential discounting, mifamurtide, NICE threshold.



## Background

In July 2011, the National Institute for Health and Clinical Excellence (NICE) published an amendment to its methods guidance for the economic evaluation of health technologies regarding the discounting of costs and health effects [1]. Since 2004, NICE has recommended equal discounting of costs and health effects at a rate of 3.5% per annum. The recent amendment, however, states that costs and health effects should now be differentially discounted at 3.5% and 1.5% per annum, respectively, in specific cases in which "treatment effects are both substantial in restoring health and sustained over a very long period (normally at least 30 years)." Such differential discounting will generally result in the health technology in question having a more favorable cost-effectiveness estimate than under equal discounting, in turn strengthening the case for its adoption.

The amendment was made following a NICE appraisal committee's consideration of mifamurtide, a drug indicated for osteosarcoma, a rare disease that principally afflicts children and young adults. An article published on NICE's Web site explained the appraisal committee's deliberation over the drug's cost-effectiveness and the decision to apply differential discounting [2]. The article notes that under NICE's standard 3.5% discount rate, mifamurtide's incremental cost-effectiveness ratio (ICER) was estimated to be £57,000 per quality-adjusted life-year (QALY), which is considerably higher than NICE's usual threshold range of £20,000 to £30,000 per QALY. The appraisal committee noted that applying differential discounting, at 3.5% and 1.5% per annum for costs and health effects, respectively, reduced the estimated ICER to a more favorable £36,000 per QALY. While this ICER remains above the threshold range, it is broadly similar to those of other interventions approved by NICE given special considerations such as disease severity and childhood disease [3], and the NICE appraisal committee recommended the adoption of mifamurtide.

In this article, we do not wish to address the merits of recommending mifamurtide. We understand and respect the appraisal committee's decision. Nevertheless, the role of NICE's selective application of differential discounting in the adoption

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decision and the subsequent amendment to NICE's methods guidance are concerning and deserve comment.

We describe how NICE's decision to recommend the selective use of differential discounting raises a number of methodological difficulties and inconsistencies. The language of NICE's amendment is also ambiguous, raising further difficulties of interpretation. These ambiguities, difficulties, and inconsistencies potentially undermine the scientific rigor of NICE's economic evaluation process.

## Ambiguities and Inconsistencies

### *Sensitivity Analysis or References Case?*

The first ambiguity is whether the differential rates of 3.5% and 1.5% are the "reference case" rates for the special cases according to the given criteria, or whether they are required only as part of a sensitivity analysis. The amendment notes that the existing NICE guidance recommends conducting a sensitivity analysis with rates between 0% and 6%, including differential discounting. The amendment states that if a sensitivity analysis is undertaken, then rates of 3.5% and 1.5% should be applied rather than the standard reference case rate of 3.5% equal discounting. The juxtaposition with the standard rate of 3.5% strongly implies that the 3.5% and 1.5% rates are the reference case rates for the special cases. Furthermore, the NICE commentary on the use of differential discounting in the appraisal of mifamurtide also supports this interpretation. The reference to sensitivity analysis, however, makes it unclear whether this interpretation is correct.

### *Eligibility for Differential Discounting*

A further ambiguity regards which cases are eligible for differential discounting. The guidance recommends differential discounting where health gains are "sustained." What is meant by sustained is not clear. It could preclude interventions that yield a long-term health gain, but only with the maintained course of an intervention rather than one-off treatment, such as HIV antiretroviral therapy. The amendment also states that the intervention must be "substantial in restoring health." Presumably this restorative criterion is intended to preclude preventative interventions. It is unclear, however, whether this requires patients to have first suffered a health decrement before the intervention alleviates this burden, or whether it is sufficient for the intervention to halt disease progression from a healthy state to a lower health state. The former would seem a strict interpretation of restoring health, while the latter would seem to apply to mifamurtide. Finally, it is also unclear how great the health effects need to be to qualify as "substantial." For example, there could be differences in the interpretation of substantial regarding relative or absolute improvements in health and whether gains need to be substantial at the individual or population level.

### *Inconsistencies Resulting from the Eligibility Criteria*

NICE's recommendation that differential discounting be selectively applied in some cases but not in others gives rise to apparent inconsistencies, whereby interventions with similar characteristics are subject to different discounting assumptions, potentially leading to large differences in cost-effectiveness. Four apparent inconsistencies are as follows:

1. If we assume that the restorative criterion precludes preventative care, then we can consider two strategies to control the same disease, one preventative and one curative, such as vaccination against the human papillomavirus and treatment for cervical cancer. Assuming that both interventions satisfy the amendment's other criteria, then, although they potentially achieve the same outcome, their effects will be discounted differently. In this case, vaccination would be disadvantaged relative to treatment in terms of cost-effectiveness.
2. Similarly, if the criterion of sustained health gain precludes interventions that require maintained therapy rather than a one-off intervention, then a maintained intervention such as antiretroviral therapy will be subject to equal discounting, while a drug such as mifamurtide enjoys the benefit of differential discounting.
3. Consider two interventions that yield the same aggregate QALY gain, one achieving this by bringing about a small QALY gain per individual in a large patient population, while another achieves a large QALY gain per individual in a small patient population. If the substantial criterion precludes the application of differential discounting in interventions with small health gains per patient, then despite having similar aggregate QALY gains, the two interventions may be subject to different discount rates.
4. Finally, consider two interventions, the first yielding benefits for 29 years, the second yielding identical benefits for 29 years and an additional benefit in the 30th year (and so only the second satisfies the "sustained" criterion). Assume that both meet the amendment's other criteria. Despite the fact that both interventions produce the same benefit for 29 of the 30 years, the second will qualify for differential discounting, while the first will not. This means that the initial 29 years of identical benefits will be valued differently by NICE's new discounting scheme, simply because the second intervention achieved one more year of benefits.

### *Discrimination on the Basis of Life Expectancy*

The criterion that health gains must be sustained for 30 years or more creates scope for arbitrary discrimination solely on the basis of life expectancy. It means that an intervention for an individual with a remaining life expectancy of 30 years could be eligible for differential discounting, whereas an intervention for an individual with marginally less remaining life expectancy would be subject to less favorable equal discounting. Consequently, there could be a large difference in the intervention's cost-effectiveness estimates between these two similar individuals, potentially leaving one individual eligible for treatment, but not the other. Such arbitrary discrimination against those with shorter life expectancy is unjustified. Furthermore, because individuals with shorter life expectancy are often (but not always) older than those with longer life expectancy, the revised discounting guidance potentially exposes NICE to accusations of ageism.

NICE has previously been accused of both ageism and discrimination against those with short life expectancy, most notably by Harris [4]. This criticism, however, has been countered by pointing out that NICE does not value health gains in older patients or those with short life expectancy less than equivalent health gains in other patients [5]. Unfortunately, with NICE's selective application of differential discounting, this defense may no longer stand in all cases.

## Theoretical Issues and the Choice of Discount Rates

NICE's amendment is also problematic regarding the discount rates it recommends. While differential discounting at rates of 3.5% and 1.5% for costs and health effects has been recommended by the Department of Health since 2004 [6], the amendment makes no reference to this guidance. Similarly, the amendment makes no reference to recent theoretical work on the appropriate discount rates. Claxton et al. [7] demonstrate that the appropriate differential between the discount rate on costs and effects depends on whether or not the health care budget is fixed. They show that in the case of a nonfixed budget, the

differential between costs and effects should equal the annual growth rate of the societal value of health. In the case of a fixed budget, the differential between the discount rates on costs and effects is not determined by growth in the societal value of health but should approximate the real annual growth rate of the cost-effectiveness threshold, with positive threshold growth corresponding to a lower discount rate for effects.

The existing NICE guidelines on the economic appraisal of health care interventions explicitly state that the National Health Service budget is assumed to be fixed [8], which implies that a lower discount rate for health effects should be justified by evidence of an increasing threshold. NICE's stated cost-effectiveness threshold range, however, has remained constant in nominal terms over recent years, implying a real-terms decrease [9]. Consequently, it is difficult to see how the 2% differential used by NICE is justified. Furthermore, Paulden and Claxton [10] show that under the perspective ostensibly adopted by NICE, the discount rate on costs should approximate the real rate of return on government bonds. The real rate of return on UK government bonds is currently far below the 3.5% used by NICE and has been for some time. Indeed, there is a notable irony that if NICE had considered this recent theoretical work and set the discount rate for costs and health effects equal to current real government bond yields, then mifamurtide might have been found to be cost-effective and there would have been no need to adopt theoretically unjustified differential discounting.

## Absence of Rationale and NICE's Citizen's Council Deliberation of Differential Discounting

An overarching problem with the amendment is the lack of a plausible rationale for the selective application of differential discounting. The amendment gives no justification for the eligibility criteria it sets, and there is no obvious reason why they should apply. While NICE gives no rationale for selective differential discounting, some insight is offered by a recent consultation of NICE's Citizen's Council of lay people. In November 2011, NICE asked its Citizen's Council to consider the issue of discounting. A final report of this consultation was published in August 2012 [11].

As part of the consultation, NICE asked the council to consider differential discounting in the context of a hypothetical example of a highly effective (curative in most cases), but very costly orphan drug used to control a childhood disease that is usually fatal if unchecked. The ICER of the hypothetical drug under 3.5% equal discounting was given as £57,000/QALY compared with £24,000/QALY under differential discounting at 3.5% and 1.5%. This example clearly and apparently deliberately resembles mifamurtide. The Citizen's Council expressed concern regarding the implications of discounting at a common rate of 3.5% per annum for the drug's cost-effectiveness. The council agreed that differential discounting should be applied in cases of highly effective or curative interventions, interventions with health effects over a long period of time, and (less unanimously) interventions for children. A majority of the council members also said that they would recommend adopting the hypothetical drug.

Despite the Citizen's Council apparent approval of differential discounting in the mifamurtide-like example, it is doubtful whether this lends credibility to NICE's selective application of differential discounting. The example presented to the Citizen's Council conflates discounting with the issues of curative care, childhood disease, and disease severity and rarity. Empirical evidence indicates that people have a stronger preference for health gains in children over adults, for health gains in those with severe illnesses over less serious conditions, and for treatment over prevention [12,13]. While there is no empirical evidence of individuals having stronger preferences for treating rare diseases, there is an apparent degree of policy support for treating rare diseases preferentially, as evidenced by financial incentives for research on such conditions in the United States and the European Union [14]. Consequently, the Citizen's Council approval of differential discounting in the mifamurtide-like example may simply be an expression of a greater willingness to adopt such an intervention, rather than an endorsement of selective differential discounting per se.

## Moving Forwards

While NICE's selective adoption of differential discounting is an easy target for criticism, we do have sympathy with those tasked with deciding whether or not to approve mifamurtide. Rejecting mifamurtide would likely prompt strong criticism of NICE by the popular press. Faced with public pressure and an apparent societal preference to prioritize curative care for severe, rare diseases in children, a degree of flexibility in this case was not unwise. However, we feel that such flexibility should be exercised in a transparent and scientifically rigorous manner. If NICE wishes to incorporate concern for particular patients or diseases into its cost-effectiveness analyses, then this should be done so explicitly through means such as adopting a higher cost-effectiveness threshold or QALY weights in clearly defined eligible cases. This approach already has precedence with NICE's consideration of "end-of-life care" and in other decisions where interventions with ICERs over the threshold range have been recommended for adoption for explicit reasons, such as disease severity, childhood illness, and significant innovation [3,15]. Similarly, the National Health Service in England has made special provision for oncology treatments with ICERs above the current threshold with the 2011-2014 Cancer Drugs Fund [16]. While we share previously articulated concerns regarding ring-fenced funding [17], it may have been more appropriate to use the Cancer Drugs Fund to accommodate mifamurtide than to arbitrarily adjust the discount rates.

In summary, NICE's recently revised discounting guidance gives rise to numerous ambiguities, difficulties, and inconsistencies, which have the potential to undermine the scientific rigor of NICE's economic evaluation process. In particular, NICE's amendment creates scope for arbitrary discrimination on the basis of life expectancy. Furthermore, the discount rates chosen are not supported by our current understanding of differential discounting. The choice of discount rates for quantitative analyses of public policy will always provoke debate, as evidenced by the controversy surrounding the discounting methodology adopted in the Stern review of the economic consequences of climate change [18–20]. Although flexibility in decision making is necessary, achieving such flexibility with an apparently ad-hoc and theoretically unjustified change to methods guidance is imprudent. We hope that NICE will consider these issues and refer to the body of theoretical research on discounting when revising its discounting methodology in the future.

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